UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): **May 19, 2020**

Oncternal Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**000-50549**	**62-1715807**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

12230 El Camino Real
Suite 300
San Diego, CA 92130
(858) 434-1113
(Address and zip code; telephone number, including area code, of registrant's principal executive offices)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	ONCT	The Nasdaq Stock Market, LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐
If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On May 19, 2020, Oncternal Therapeutics, Inc. ("Oncternal" or the "Company") announced updated interim clinical data from the ongoing Phase 1/2 CIRLL (Cirmtuzumab and Ibrutinib targeting ROR1 for Leukemia and Lymphoma) clinical trial, in which cirmtuzumab, an investigational anti-ROR1 monoclonal antibody, is being evaluated in combination with ibrutinib in patients with mantle cell lymphoma ("MCL") or chronic lymphocytic leukemia ("CLL"). The data will be presented as part of the American Society of Clinical Oncology ("ASCO") 2020 Virtual Annual Meeting on May 29, 2020.

As of the data cut-off date of April 30, 2020, 15 patients with relapsed/refractory MCL were enrolled in the dose-finding and dose-confirming cohorts of this clinical trial, 12 of whom were evaluable for efficacy:

- Seven of the 12 evaluable patients achieved a complete response, for a complete response ("CR") rate of 58%, determined by Cheson criteria. One of the seven patients had a complete metabolic response ("CMR") by PET scan, with an indeterminant bone marrow biopsy. Responses developed rapidly in most patients, with four of the seven CRs documented after approximately three months on the combination of cirmtuzumab and ibrutinib. All seven CRs were ongoing, including one patient who has remained in CR at over 23 months on study.
- The overall best objective response rate ("ORR") was 83%, including patients who achieved a CR and three patients (25%) who achieved a partial response ("PR"). In addition, two patients had stable disease ("SD"), for a total best clinical benefit rate (including CR, PR and SD) of 100%.
- Median progression-free survival ("PFS") was 17.5 months, with a median follow-up of 8.3 months.

- Patients had received an average of 2.8 prior therapies (range 1-5) before participating in this clinical trial, including four patients who had received prior treatment with ibrutinib. Seven of the 12 evaluable patients had high or intermediate Mantle Cell Lymphoma International Prognostic Index ("MIPI") risk score at study entry.
- Historical data published for single-agent ibrutinib for patients with MCL, who had received more than one prior therapy, reported an ORR of 63%, CR rate of 23% and median PFS of 10.3 months (Rule 2019 Haematologica).

As of the data cut-off date on April 30, 2020, 34 patients with CLL were enrolled in the dose-finding and dose-confirming cohorts of this clinical trial, all of whom were evaluable for efficacy:

- Thirty of the 34 evaluable patients achieved a clinical response, for an overall best ORR of 88%, including one patient (3%) who achieved a CR, and 29 patients (85%) who achieved a PR. In addition, four patients had stable disease, for a total clinical benefit rate (including CR, PR, SD) of 100%.
- No patients progressed while in the study, and PFS was 100%, with a median follow-up of 12.8 months.

- Twelve patients were treatment-naïve and 22 had relapsed/refractory CLL. Patients with relapsed/refractory CLL had received an average of 2.6 prior therapies (range 1-9) before participating in this clinical trial.

Cirmtuzumab as a single agent has been well tolerated in this study. The combination of cirmtuzumab plus ibrutinib has also been well tolerated, with adverse events consistent with those reported for ibrutinib alone. There have been no dose-limiting toxicities and no serious adverse events attributed to cirmtuzumab alone. Neutropenia of any grade occurred in six subjects (8.6%).

Cautionary Note Regarding Forward-Looking Statements

Oncternal cautions you that statements included in this report that are not a description of historical facts are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negatives of these terms or other similar expressions. These statements are based on the company's current beliefs and expectations. Forward looking statements include statements regarding Oncternal's beliefs, goals, intentions and expectations, and include: the potential of cirmtuzumab to treat ROR1 expressing cancers, and the potential for interim data results to be replicated or continue to show improved clinical efficacy as the ongoing trial continues. Forward looking statements are subject to risks and uncertainties inherent in Oncternal's business, which include, but are not limited to: the risk that interim results of a clinical trial do not necessarily predict final results and that one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data, and as more patient data become available, including interim response results may not be confirmed by later assessments; the risk that unforeseen adverse reactions or side effects may occur in the course of developing and testing product candidates such as cirmtuzumab and

Oncternal's other product candidates, which could adversely impact the company's ability to complete clinical trials and obtain regulatory approval for such product candidates; Oncternal has encountered delays, and may encounter additional delays or difficulties, in enrolling patients in its clinical trials as a result of the COVID-19 pandemic; the COVID-19 pandemic may disrupt Oncternal's business operations, increasing its costs; uncertainties associated with the clinical development and process for obtaining regulatory approval of cirmtuzumab and Oncternal's other product candidates, including potential delays in the commencement, enrollment and completion of clinical trials; Oncternal's dependence on the success of cirmtuzumab and its other product development programs; the risk that the regulatory landscape that applies to the development program for cirmtuzumab and the company's other product; comparisons to historical ibrutinib data are based on unrelated clinical trials and does not reflect results that might have been obtained from head-to-head studies, including due to differences in study protocols, conditions and patient populations; candidates may change, which could result in delays or termination of development of such product candidates or unexpected costs in obtaining regulatory approvals; the risk that competitors may develop technologies or product candidates more rapidly than Oncternal, or that are more effective than Oncternal's product candidates, which could significantly jeopardize Oncternal's ability to develop and successfully commercialize its product candidates; Oncternal's limited operating history and the fact that it has incurred significant losses, and expects to continue to incur significant losses for the foreseeable future; the risk that the company will have insufficient funds to finances its operations after the third quarter of 2020 and may not be able to obtain sufficient additional financing when needed or at all as required to achieve its goals, which could force the company to delay, limit, reduce or terminate its product development programs or other operations, and other risks described in the company's prior public periodic filings with the U.S. Securities & Exchange Commission. All forward-looking statements in this report are current only as of the date hereof and, except as required by applicable law, Oncternal undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Oncternal Therapeutics, Inc.

Date: May 19, 2020

By: /s/ James B. Breitmeyer

Name: James B. Breitmeyer, M.D., Ph.D.

Title: President and Chief Executive Officer